Radio Frequency Identification Tags (RFID) Configuration Application for Medical Device Industry Supply Chain using DMAIC Methodology

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Abstract - To align data control at inner cell an RFID Configuration Application was developed with the intend to reduce lost traceability issues. Six Sigma strategy following the DMAIC methodology was used as guidance to define the problem, measure the current state quo, analyze the problem, perform an improvement, and control the process. Through this project, the product changeover time at workstation 2 was eliminated (48s for a total available time of 80 min per day), and other design, and administration wastes as motion, overprocessing and defects (Non-conformances due to "Lost Traceability" that resulted on scrap were eliminated by 100%). This project helped to reach a labor cost avoidance of $2,558.88 and helped to increase 51% of the workstation capacity per day, and to creates a surge capacity of 63 units per day required for an upcoming project. Furthermore, improved the operators (customer) satisfaction, as well as the support team.

The RFID Configuration Application implementation achieve its objective of Improving the product identification and traceability contributing to maintains the process in compliance as required by applicable regulatory bodies in Puerto Rico for Medical Devices Industry.

Project Description

The intend of this project is to improve the information recording method currently used for Product B and align it with current method in place for product A, in order to trace the data systematically and facilitate the product changeover activities. This project has been chosen to mitigate a data control vulnerability detected as part of Workstation Vulnerability Assessment Project. The Medical Device Industry is a highly regulated industry, under the FDA 21 CFR 820 and 821, therefore, this project will ensure compliance with the regulation, as well as improve quality, cost and time.

Project Objectives

- Improve the product identification and traceability of workstation 2 by 100% using passive RFID Technology
- Reduce the workstation 2 changeover time of 48 s
- Increase the workstation 2 daily output to 32 additional units per day

Project Contributions

- Data Control (Get correct traceability data systematically through passive RFID Technology)
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- Data Control (Get correct traceability data systematically through passive RFID Technology)
- Product Changeover Time (Reducing the change over labor cost)
- Eliminate Manufacturing Wastes (Motion, Overprocessing, Defects)
- Efficiency (Increase daily output and allows the support teamwork focus on other projects, etc.)
- Increase the customer satisfaction (Operators)

Literature Review

Manufacturing competitiveness and "world-class manufacturing" (WCM) are often used interchangeably. Manufacturing competitiveness promote the growth and earrings by creating high value products which build and lead the customers loyalty [1]. WCM consist in seven approaches: Safety and Environment, Reliability and Availability, Quality and Yield, Performance, Rationalization in logistics and manning, Synchronization between the sales, and Fully automated plant [2].

U.S Food & Drug Administration has developed Federal Regulations for Health and Human Services. Part 820 Quality System Regulations for Medical Devices stablishes the guidelines for product identification and traceability [3]. Companies best-practice is to record a traceability matrix of a product to show the linkages and relationship between User Needs,

Design Inputs, Design Outputs, Design Verification, and Design Validation. The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements [4].

Build in Quality in Medical Devices include take into consideration Design Control, Risk Management, Document Control & Record Management, and supplier Management. In Aurora Line, that manufactures Product A and Product B (Similar products), recorded the Products Traceability Data (i.e. Component ID, Batch No., Operator, Date, etc) through Radio Frequency Identification (RFID) Tags and Ports. Then data collected thorough the RFID System is recorded electronically in Manufacturing Execution System (MES). This system autogenerate the Device History Record (DHR) which allows an easy access to product information. This is required for maintaining, and availability for inspections, as well as audits.

RFID is a technology that uses radio waves to transfer data from an electronic tag, called RFID tag or label, attached to an object, through a reader for the purpose of identifying and tracking the object [5]. RFID technologies are becoming more sophisticated over the time. There are two types of RFID: active or passive. Active RFID tags needs a battery because are commonly used as "beacons" to accurately track the real-time location of assets; while passive tag does not have an internal power source because uses an electromagnetic energy that is transmitted from and RFID reader. Passive RFIDs tags are used for many applications as smart labels, access control, file tracking, supply chain management, among other processes. This technology promises more control and larger savings to companies that handle high volume of products [6]. Supply Management of big companies as Wall-Mart, Procter & Gamble, and the US Department of Defense are moving forward tagging the items within its transactional processes in order to maintains a real time inventory [7]. The data collection method based on RFID technology is very convenient because allow the companies to be agile, reduced manpower, saved time, improved data accuracy, and helped to automate the manufacturing process.

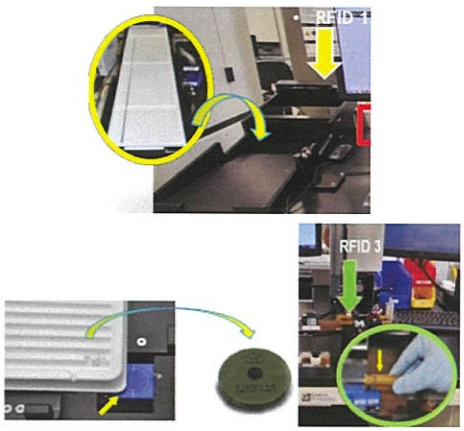

Figure 1 - RFID Reader (Blue square) and Passive RFID Tag (black Circle that is placed within the white Tray and inside the yellow Fixture that is held by the hand

Methodology

Quality Management Systems used DMAIC methodology for process improvement because is a data-driven strategy.

- **Define**

Work instructions, process flowchart, and validation documents were read to understand the process before performing the Workstation Vulnerability Assessment. During the assessment operators and support team were interviewed and a brainstorming session was performed to capture workstation necessities and collect ideas. Then, these ideas were organized into an affinity diagram. A Project Charter was developed to explain the possible project to the core team.

- **Measure**

Time Studies were performed to understand how different is recording the data from product A Vs. Product B. Then, a value stream map for inner cell was build taking into consideration cycle time, material, changeover time, material movements, etc.

- **Analyze**

To understand how different variables can affect the process a fishbone analysis was included in the analysis. The output of the fishbone helped to create a Failure Mode and Effect Analysis, what helped to organize what are the process inputs and how process variables can affect the process output. These activities were key to perform a Process Change Analysis that anticipate possible activities necessaries to conduct the change and its impact. Furthermore, MES Reports were accessed to understand what non-conformances are related to Data Control.

- **Improve**

RFID Configuration Application was developed. Trial runs were performed to make sure that the application works. Then, documentation generation (Work Instructions, Safety Risk, Drug Triage, Change Notice Impact, CAPA Search, etc) was completed after trials were confirmed to be

successful. Change was presented to compliance and implementation date was set.

- **Control**

Trainings was provided to the operators, and after being documented on training system, the change was placed as effective and could be used on manufacturing area. Feedback from operators was collected and MES Report were accessed to monitor completions and non-conformances for Lost Traceability Issue.

Results and Discussions

A Workstation Vulnerability Assessment (Evaluates People, Method, Material, Measurement, and Equipment) in "Aurora" Line triggered Workstation 2 within inner cell in red, what makes that inner cell turns to red as shown in Figure 2.

Figure 2 - Results per Cell of Workstation Vulnerability Assessment for Aurora Line

Figure 3 shows Inner Cell that is comprised of four (4) workstations. The first one a decision must be made (Diamond), the second and third ones are process steps (square) and the last one is part of a movement transaction to be storage (inverted triangle).

Figure 3 - Inner Cell at Aurora Line

Each of these topics were discusses. For example, staff was discarded because it was found that this working cell have 3 product builders, and already are 4 processes. There are about 1 Manufacturing Engineer and 1 Quality Engineer as well as a supervisor and line coordinator. Education and communication were discarded because all the product builders are certified in the workstation, the working cell have a daily meeting to discuss the plan, as well as an extra meeting to discuss the performance. Regarding with the environment, was found that there are three workstation that realizes de same process, and no working pressure is exerted to the inner cell team. Materials was discarded as well because there are enough trays, RFID readers and tags. Nevertheless, it was found that work instructions guide the operators to use the RFID readers to get the data, but when operators try to get the data making use of the RFID readier were unable. This activity helps to understand that works instructions were not aligned with the current process. Further investigation, and software representative intervention helps to realize that "Data Control for Lost Traceability Issue" iwas due to RFID port. RFID port are defined per default for a data reader. Product A generates the product traceability using on RFID port no. 3 (Refer to Figure 1), while Product B already have traceability generated and its suppose to start reading in the RFID port no. 1 (Refer to Figure 1), because the product was already generated in the first workstation of the workflow (Refer to Figure 3).

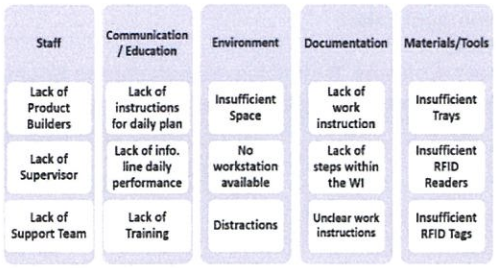

Figure 4 - Affinity Diagram

A brainstorming session was performed with operators and support team with the purpose to record ideas that could help the production team to run both products simultaneously. For each of the ideas was took into consideration the 'pros' and 'cons' as well as the resources needed. A final raking was given to make clear the viability of the possible project. Refer to Table 1.

Idea	Pros	Cons	Contributor	Ranking
Dedicate 1 out of 3 workstataion for product B	Avoid Product changeover	Versatility	Production	6
Enable a 4th workstation for Product B	Increase Capacity	Space	ME/Industrial	8
Creates a container in Workstation 2	Align both process	Validatation	SW Res./Yane	2
Print lables with info to 100% of the trays	A kind of paka joke	Waste (Trash)	Operator	5
Reconcile 100% produced per hour	Data Verification	Waste (Time)	Dispositioner	3
Configure the RFID for every changeover	None	Waste (Time)	Operator	1
RFID Conf. Application	Versatilty and Increase Capacity	Change Notice	SW Rep./Yane	10

Table 1 - Brainstorming Session Outcome

Enable another workstation was discarded because there's no enough space in the manufacturing room. Dedicate 1 out of 3 workstations will decrease the versatility metric of the line (as well as capacity). Attempt to start the *Product B* as the same has been set for *Product A* will incur in changing the current validation documentation which was not viable because the validation documentation was being reviewed by regulatory bodies because the product launch. Continue printing labels neither was viable because the waste of labels

Project Name: RFID Configuration Application
Project Manager: Yaneira González
Team Member: Industrial Engineer, Software Technician, Manufacturing Engineer, Design Engineer

Project Scope

Problem Description	Trays without traceability information at inner cell
Business Necessity	Trays that have its traceability information as required by regulatory bodies (ISO & FDA) to continue it build process.
Project Description Elevator Pitch	Implement the RFID Configuration App with the purpose to record the traceability information of Product A and Product B, without discrepancies when product changeover occurs.
Project Timeline	Dic 2020 to May 2021
Benefits	- Data Control (Get correct traceability data) - Yield (Decrease the scrap) - Change over Time (Promote continue line flow) - Efficiency (less Non-Conformance, less Operators to reach the daily output, support teamwork focus on other projects, etc) - Eliminate Waste (Labels Printing, Material Scrap, Time Consumption) - Increase the customer satisfaction (Operators) - Save Time (Investigation Time) - Maintains the lines flow
Scope	In a time of 3 months implement an RFID configuration app project with the purpose to record the traceability information of Product A and Product B and maintains the lines flow healthy.
Finance	Over $3,000 annually
Risk & Mitigations	- Product Builders don't able to sign in → Make sure to give the training and recording on system - Product Builder idon't select the correct item in the HMI (Icon for product A Vs Icon for product B) → Configure each icon with the product specific part number
Potential Problems	• Product builders unable to sign in into the process because TRS data entry process.
Critical Step	• Product builder accessing the system without selecting the icon in the HMI

Project Schedule

Milestone		Goal	Actual Tracking
Define	RFID Configuration Application Development	1/29/2021	Done
Planification	• Identify the project requirements an organized in a Gantt chart	2/5/2021	Done
Execution	Execution: • PCA (CAF) document generation and approval • Non-Impact Change Analysis Run • Implementation • Training	3/9/2021	On Track
	Measure • SIPOC • Gantt chart • Time Studies • CO Cost Avoidance • Scrap Variance • Material Consumption	5/5/2021	On Track
Monitoring/ Controlling	• MES Reports • Voice of Customers	5/5/2021	Pending

Project Status

Progress Last 30 days	System Configuration Process Development Time Studies Value Stream Map Fishbone Diagram PFM
Plan: *Next 30 days:*	• Non-Impact Change Analysis • Trials Run • Change Notice Documentation (WI, PCA, Drug Triage, Safety Triage, CAPA Search) • Request the regulatory meeting
Support or Next Decision	• Provide the trainings • Regulatory/Compliance Team to perform the change documentation review

Figura 5 - Projct Charter

and ink and the risk of stick in other trays remains. Reconciliate the 100% of the trays is not an option because a significant part of the product is consumed constantly and reconciliate the remaining physical material with the reports will take a lot of time. Configure the RFID by hand every time product change over occurs also was not viable because will activate the Watch dog systems that monitor the systems files integrity. While, that investing time in the development of an RFID configuration application will help to create a solution with a simple change notice, will not affect the validation, and will takes less time. A Project Charter (Refer to Figure 5) was created to show the team the project plan.

Time studies were performed at inner cell area to understand the time is consumed when building *Product A* Vs. *Product B*. The average lectures in Workstation 2 for *Product A* was 51 seconds, while for *Product B* was 115s (Table 2).

Lecture	Product A Process CT (sec.)	Product B Process CT (sec.)
1	47	114
2	54	115
3	51	114
4	50	117
5	54	114
6	56	113
7	47	114
8	53	115
9	51	113
10	51	115
11	54	118
12	50	114
13	48	116
14	52	115
15	51	120
Average	51	115
Max	56	120
Min	47	113
Range	9	7

Table 2 - Time Studies in Workstation 2

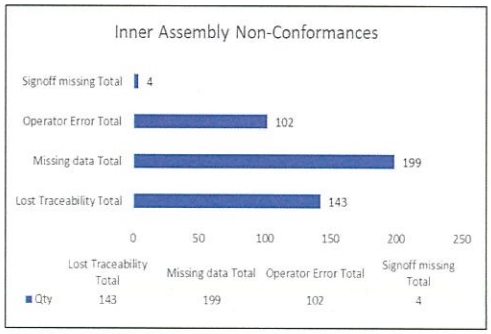

Figure 7 - Inner Assembly Non Conformances realted with Data Control

Those products are similar but components and its interaction are different, hence could be understood the observed difference in time. Data was used to build a value stream map (Refer to Figure 6).

MES Non-Conformance and Scrap Report were accessed to understand what kind of "defects" were associated to "Data Control" or "Data Management". Four (4) kind of reason codes were found: Signoff Missing, Operator Error, Missing Data and Lost Traceability.

- **Sign off Information**- is when product builders are unable to read the information because there 'were a power failure that debilitated the system momentously.
- **Operator Error** – Operator perform a split incorrectly

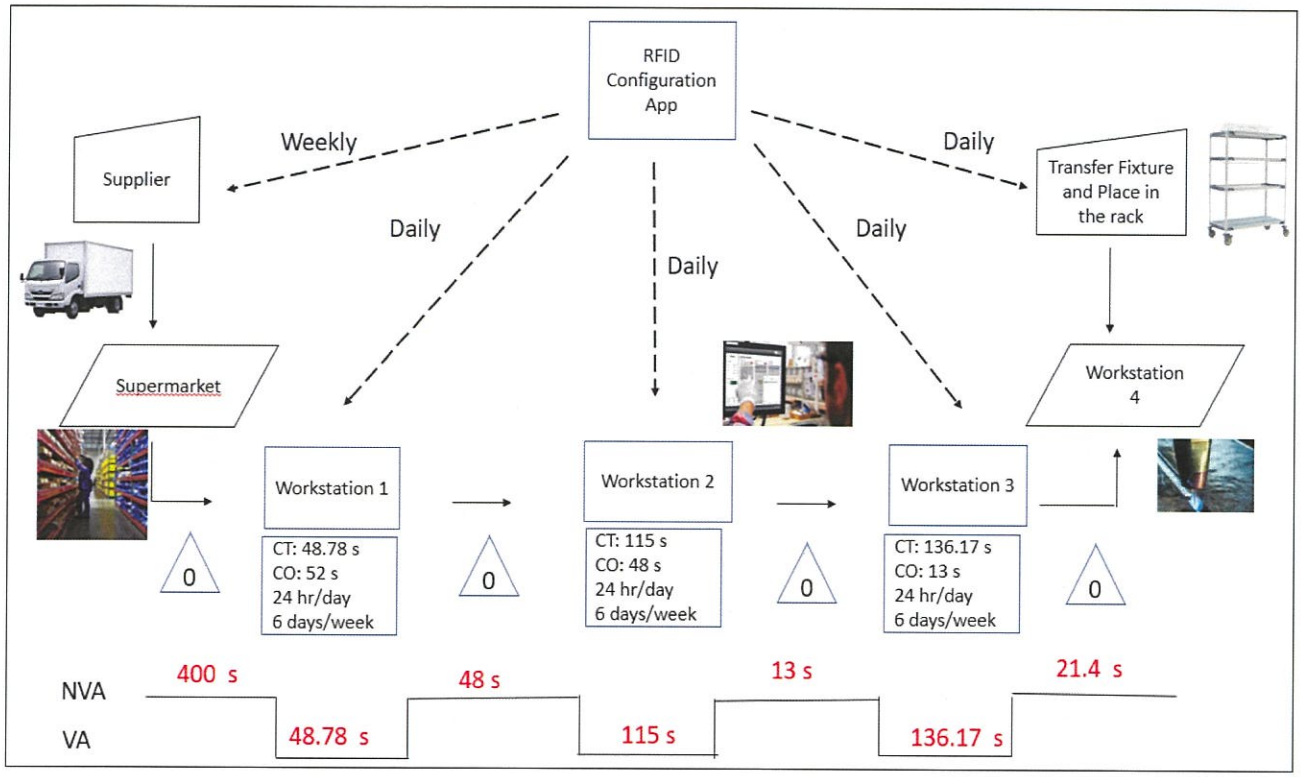

Figure 6 - Value Strem Map

and scrapped the material by error

- **Missing Data**- When operators have selected a recipe and loaded other material (i.e physically there are "long" coils in the tray but signed off in the system as were "short" coils).
- **Lost Traceability**- Trays does not have any kind of information.

Sub-Assemblies cost depends on the length and product. Prices fluctuated between 30.00 to $38.00. Scrapping a tray of 12 sub-assemblies because a "lost traceability issue" have an econmic impact of $456.00.

In order to understand what issues can be triggering the lost traceability issue at Workstation 2, a Fishbone Diagram Tool (Figure 8) was used. This tool allowed to break down the process input taking into consideration machine, material, method, environment, man and measure. After performing the fishbone, it was necessary to perform a verification of each of the potential causes to prove or discard is having a direct influence on the lost traceability issue. Table 3 column 4 explain what kind of verification was performed. Table 3 shows the category, cause, evidence of source and its effect on the project, while Table 4 show the actions taken as part of the evaluation, and its possible solution.

Item	Category	Cause	Evidence Source	Affects?
1	Machine	Recipe Error	Recipe Review and Gemba Walk	NO
2	Machine	Software /Configuration RFID	System Verification and Gemba walk	YES
3	Machine	MES / PIA	System Verification	YES
4	Material	Material Handling	Gemba walk	YES
5	Material	Material Identification	Gemba Walk	YES
6	Material	Trays Physical Condition	Gemba Walk	YES
7	Method	Work Instructions (WI)	Documentation Review and Process Monitoring	YES
8	Method	Training	Curriculum Review	YES
9	Method	RFID / Scanners	Gemba walk	NO
10	Environment	Layout	Gemba Walk	NO
11	Environment	Distractions	Gemba Walk, Interviews	NO
12	Environment	Illumination	Gemba Walk	NO
13	Man	Choose Incorrect Recipe	Gemba Walk	NO
14	Man	Perform a step wrongly	Gemba Walk	YES
15	Man	Skip a step	Gemba Walk	NO
16	Measure	N/A	N/A	N/A

Table 3 - Cause Evaluation

The **root cause** for "Lost Traceability Issues" were due to RFID Configuration Capability. The RFIDs ports can be configured as required, but PIA Systems monitors the software's

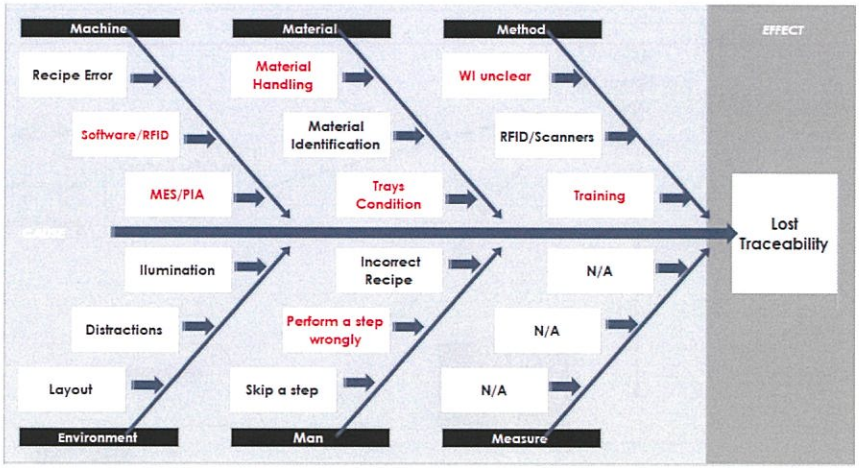

Figure 8 - Fishbone Diagram for Lost Traceabiltiy Issue

No.	Cause	Actions	Effect on Project?	Possible Solution
1	Software /Configuration RFID	RFID Function Capability was tested to understand its functionality. It was found that RFID port are fixed. Its configuration is being monitored by PIA.	YES	Creates different RFID configurations files.
3	MES / PIA	MES/PIA configuration for this process was verified and it was found to be correctly. However, it was found that PIA controls the recipe parameters (which include the RFID port set up). In this case, if product builders try to change the RFID configuration manually in PIA files, watch dog will trigger an alarm, and the process will automatically stop. The process can't be re-initiated without technical support intervention/investigation.	YES	N/A. PIA is performing its intended work
4	Material Handling	A walk up through supermarket to understand the storage process. The workstation material handling was observed in several shifts to understand the product behavior when handling the material.	NO	Material Handling should be addressed through operators
5	Material Identification	The Material Identification it's supposed to be recorded through the RFID tag. Operators are currently printing the labels.	NO	Don't allow to use the MES printer
6	Trays Physical Condition	The Trays inventory was inspected to see if shows physical damages that might be interfering in the tray loading position in the workstation.	NO	Perform and inventory verification and scrap those that are in bad condition or have physical damage. Buy new ones if necessary.
7	Work Instructions (WI)	The work instruction was reviewed in detail and it was found that the process can't be executed as stated in the document.	YES	Modify the steps
8	Training	Because the work instructions have opportunity areas will be necessary to perform a re-training once updated the work instructions.	YES	Re-training the staff
14	Perform a step wrongly	Operators are printing labels because the process can't be performed as currently stated in the work instructions	YES	Correct the Product Builders behavior once the steps has been modified in the work instruction

Table 4 - Actions to the Causes and Possible Solution

files in the equipment's. An attempt from product builders to perform this action triggers in alarms, the operators avoided printing labels with the information. The root cause for "Lost Traceability Issues" were due to RFID Configuration Capability. The RFIDs ports can be configured as required, but PIA Systems monitors the software's files in the equipment's. An attempt from product builders to perform this action triggers in alarms, the operators avoided printing labels with the information.

The **solution** was to creates two different PIA data bases (one for product A and the second one for product B), allowing to create files with distinct RFID configurations according with the product requirements. These two RFIDs configurations files can be accessed through executable shortcuts in the HMI. The executable shortcut must be selected before starting the regular "log in" process, which means that will change the instruction and product builder's behavior. Hence, work instructions must also to be updated to include the new steps as well as the illustration that works as a guidance.

To understand the scope of the project a Process Change Analysis (PCA) Form was completed. PCA procedure organizes hypothetical changes in different categories. Explains how the processes works within the organization, as well as the requirements (documents revision, regulatory meetings, design consults, system configuration, etc). This form include the rational for the change (How is the process before and after), scope of the change (Product, Process, site, etc), Risk Analysis (Review of Risk Documentation), Validation Impact (Master Validation Plan, Installation Qualification / Software Qualification, Process Qualification, Test Method Validation, Process Characterization, Design Documentation, among other things).

After PCA was completed no poroduct impact was found. Application was run, and all the test passes, however it was found that process needs to be poke-joke. Hence, each data bases accessed through the executable shortcut were configured to includ only the part numbers corresponding to each product, avoiding that product builders selects the incorrect configuration file.

Having passes all the test and knowing the process opportunities, next phase which was update the work instruction (Refer to 9). Nevertheless, production documents update always requires

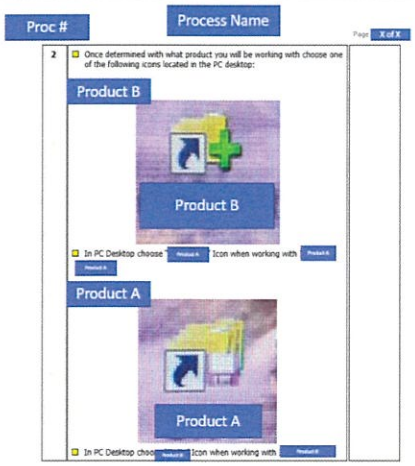

Figure 9 - Polytechnic University Logo

documenting a Change Notice through Windchill System (integral software package for Manufacturing Process Management), as well as present the change to the Organization Regulatory Body.

After change implementation (RFID Configuration application) and re-training was given, the process cycle time of Product B was recorded for Workstation 2.

Product B		
Lecture	Process CT (sec.)	
	Before	After
1	114	85
2	115	77
3	114	73
4	117	80
5	114	76
6	113	78
7	114	73
8	115	76
9	113	81
10	115	72
11	118	76
12	114	76
13	116	70
14	115	77
15	120	74
Average	115	76
Max	120	85
Min	113	70

Table 5 - Cycle Ttime after the Change Implementation

Workstation 2	Product B Cycle Time	Equip Qty.	Uptime	Shifts	Yield	Capacity / Day
Before	115	3	100%	1210	1.50%	1866
After	76	3	100%	1210	1.50%	2823
						957

Table 6 - Worstation 2 Capacity Before and After the Project

Frequency/ Shift	Shift per day	Time CO (sec.)	Total CO (min.)	Labor Cost	Days per month	CO Labor Cost per Day	CO Labor Cost per Year
50	2	48	80.00	17.77	9	$213.24	$2,558.88

Table 7 - Change Over Labor Cost Avoidance for Product B

Process / Station	Process CT (sec.)	Frequency/ Shift	Shift per day	Time CO (sec.)	Total CO (min.)	Process Efficiency	Potential Units
Workstation 2	76	50	2	48	80.00	95%	63

Table 8 - Process Efficiency and Potential Additional Units

An average of 76 s was obtained as tabulated in Table 5. Furthermore, changeover time due to the RFID configuration decrease from 48s to 0s. because product builders do not have to configure the RFID ports anymore. Just place the trays in the corresponding RFID and the system automatically read the information, and they can start assembling the lead.

The difference is around 39 seconds. There are different reasons: a component measurement variance was controlled (Via Supplier correction, not related with this project but have an impact on process cycle time), and also, because the retraining.

Having a Workstation Cycle time of 76s, three equipment's available with a uptime of 100%, and the net available time of 1210 min (24 hr or 1440 min less breaks, gowning (Enter and Exit), stand up meeting, and personal break) have a capacity of 2,823 assemblies per day, 957 sub-assemblies more than what when the line started up. Refer to Table 6.

The workstation production has a

$$\textbf{Capacity Increase} = \frac{\textit{New Capacity} - \textit{Origianal Capacity}}{\textit{Original Capacity}} \quad (1)$$

frequency of (50 trays per shift for a daily total of 100 trays) with the time that previously took to perform the changeover (48 s) gives a Total Change over time 80 min. Having a labor cost of $17.77 and running the product B nine (9) days a month, a changeover time labor cost per day is $426.48. Following equation 2, the total annual labor cost avoidance $2,558.88 as show in Table 7.

$$\textbf{Labor Cost Avoidance} = \textit{Saved CO Time} * \textit{Labor Cost} * \textit{Days per year worked} \quad (2)$$

The new process efficiency is 95% and was calculated taking into consideration the process cycle time (76s), the number of trays processed per shift (50), 2 shifts of 12hr per day, the changeover time (48s), and the daily required output (1,200 sub-assemblies) following Equation 3.

$$\textbf{Process Effciency} = \frac{\textit{Ideal Cycle Time} * \textit{Processed Amount}}{\textit{Operating Time}} \quad (3)$$

Before the change the cycle time was 115 s, for a daily output of 42 trays per shift. Saving 48 sec of changeover per tray (80 min/ day), it was suppose to potentially produce 35 additional units following Equation 4. After implementation, the cycle time was reduced to 76s, which increased to 63 additional potential units per day (Table 8).

$$\textbf{Potential Additional Units} = \textit{Daily Output} - \textit{Daily Outout (Process Efficiency)} \quad (4)$$

Because the RFID allows to record the information electroni-

cally through RFID Tags, labels with trace data are not necessary anymore. Recording the information in labels has an additional cost that was calculated taking into consideration the information included in Table 9.. The total annual cost avoidance is about $2,592.00.

Inner Cell Daily Output (2 shift)	1200
Product B Production days/month	9
Labels/package	1000
Label Package cost	$ 20.00
MES Printer Label Cost ($)	$ 216.00
Annual Cost Avoidance ($)	$ 2,592.00

Table 9 - FMES Label Cost

Figure 10 shows the scrap data due to Data Control. This project reached to eliminate the scrap due to "Lost Traceability" variable. However, further projects need to be developed to address other data control non-conformances as missing data and operator error.

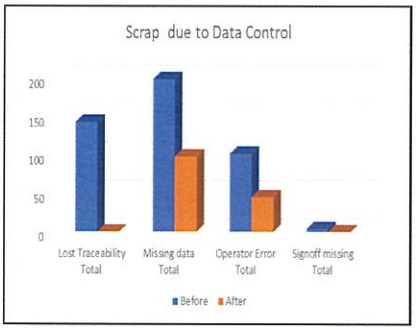

Figure 10 - Scrap due to Data Control

Conclusion

RFID Configuration Application was developed and implemented successfully after a "Data Control" opportunity was identified during a Workstation Vulnerability Assessment. Six Sigma strategy following the DMAIC methodology was used as guidance to define the problem, measure the current state quo, analyze the problem perform and improvement and control the process.

This application improved the RFID ports configuration when product changeovers has to be performed allowing to maintain the product traceability as required by the regulatory bodies as Food Drug Administration (FDA), Medical Device Single Audit Program (MDSAP) and the European Union (EU). This project contributes satisfactory to decrease the changeover (from 48s to 0s), a labor cost avoidance of $2,558.88, reduce waste (Overprocessing [MES labels: $2,592], defects [100% of non-conformances due lost traceability], motion [ask for support]), and staff investigations. Furthermore, helped to increase the daily output (create a surge capacity of 63 sub-assemblies at inner cell). This project promoted to maintains the line flow and, to increase the product builder's satisfaction.

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